

AMENDED IN SENATE JUNE 26, 2007

AMENDED IN ASSEMBLY APRIL 11, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL

No. 1442

Introduced by Assembly Member Feuer

February 23, 2007

An act to add Section 1220.2 to the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, as amended, Feuer. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law authorizes the department to adopt or repeal any regulations necessary for the administration or enforcement of these provisions *regulations require a person or entity to meet certain requirements in order to perform tests to detect antibodies to human immunodeficiency virus.*

This bill would *alternatively* require the department to repeal certain regulations requiring approval of a laboratory for use of the human immunodeficiency virus (HIV) antibody test. The bill would require a clinical laboratory performing *certain* tests or examinations to screen for HIV antibodies to ~~use only~~ *meet specified requirements, including using* a United States Food and Drug Administration approved kit, ~~to enroll~~ *enrolling* in a proficiency testing program approved by the Centers for Medicare and Medicaid Services, ~~to possess~~ *possessing* the appropriate license or registration, as specified, ~~and to confirm~~ *confirming* all screened positive, inconclusive, or indeterminate results

with a different, more specific confirmatory test prior to reporting the result, *annually reporting to the department the number and results of tests performed, and maintaining records of tests and test results in a manner to ensure patient confidentiality.*

Because the bill would revise requirements pertaining to clinical laboratories, a violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1220.2 is added to the Business and
2 Professions Code, to read:

3 1220.2. ~~At~~*In lieu of the requirements of Section 1230 of Title*
4 *17 of the California Code of Regulations, all* clinical laboratories
5 that perform tests or examinations to screen for human
6 immunodeficiency virus (HIV) antibodies, *that are classified as*
7 *waived under CLIA*, shall do all of the following:

8 (a) Utilize only United States Food and Drug Administration
9 approved kits used in accordance with the manufacturers'
10 instructions.

11 (b) Enroll in a proficiency testing program approved by the
12 Centers for Medicare and Medicaid Services.

13 (c) Possess the license or registration appropriate for the type
14 and complexity of tests or examinations performed.

15 (d) Confirm all screened positive, inconclusive, or indeterminate
16 results with a different, more specific confirmatory test prior to
17 reporting the result.

18 (e) *Report to the department, on an annual basis, the number*
19 *and results of tests performed.*

20 (f) *Maintain records of tests and test results in a manner to*
21 *ensure a patient's confidentiality.*

22 ~~SEC. 2. The department shall repeal Section 1230 of Title 17~~
23 ~~of the California Code of Regulations.~~

1 ~~SEC. 3.~~

2 *SEC. 2.* No reimbursement is required by this act pursuant to
3 Section 6 of Article XIII B of the California Constitution because
4 the only costs that may be incurred by a local agency or school
5 district will be incurred because this act creates a new crime or
6 infraction, eliminates a crime or infraction, or changes the penalty
7 for a crime or infraction, within the meaning of Section 17556 of
8 the Government Code, or changes the definition of a crime within
9 the meaning of Section 6 of Article XIII B of the California
10 Constitution.

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